United States Patent [19]

Dietrich et al.

[11] **3,941,126**

[45] **Mar. 2, 1976**

[54] **APPARATUS FOR LONG TERM INTRAVENOUS ADMINISTRATION OF DILUTED INCOMPATIBLE MULTIPLE MEDICATIONS**

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[22] Filed: **Aug. 8, 1974**

[21] Appl. No.: **495,652**

[52] U.S. Cl. ..... **128/214 R**; 128/214 C; 128/214.2; 222/81

[51] Int. Cl.[2] **A61M 5/14**

[58] Field of Search ..... 128/214 R, 214 A, 214 C, 128/214.2, 227; 222/80, 81, 426, 430

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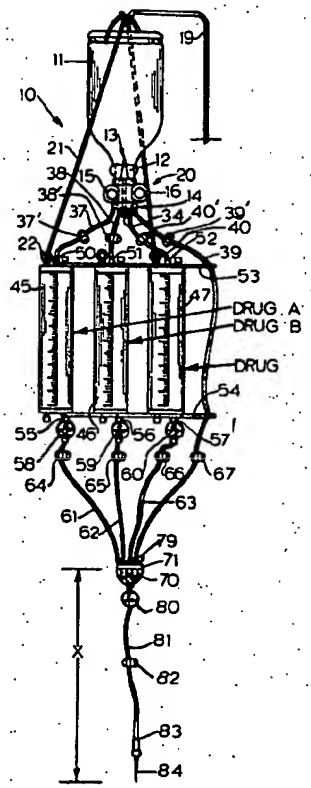
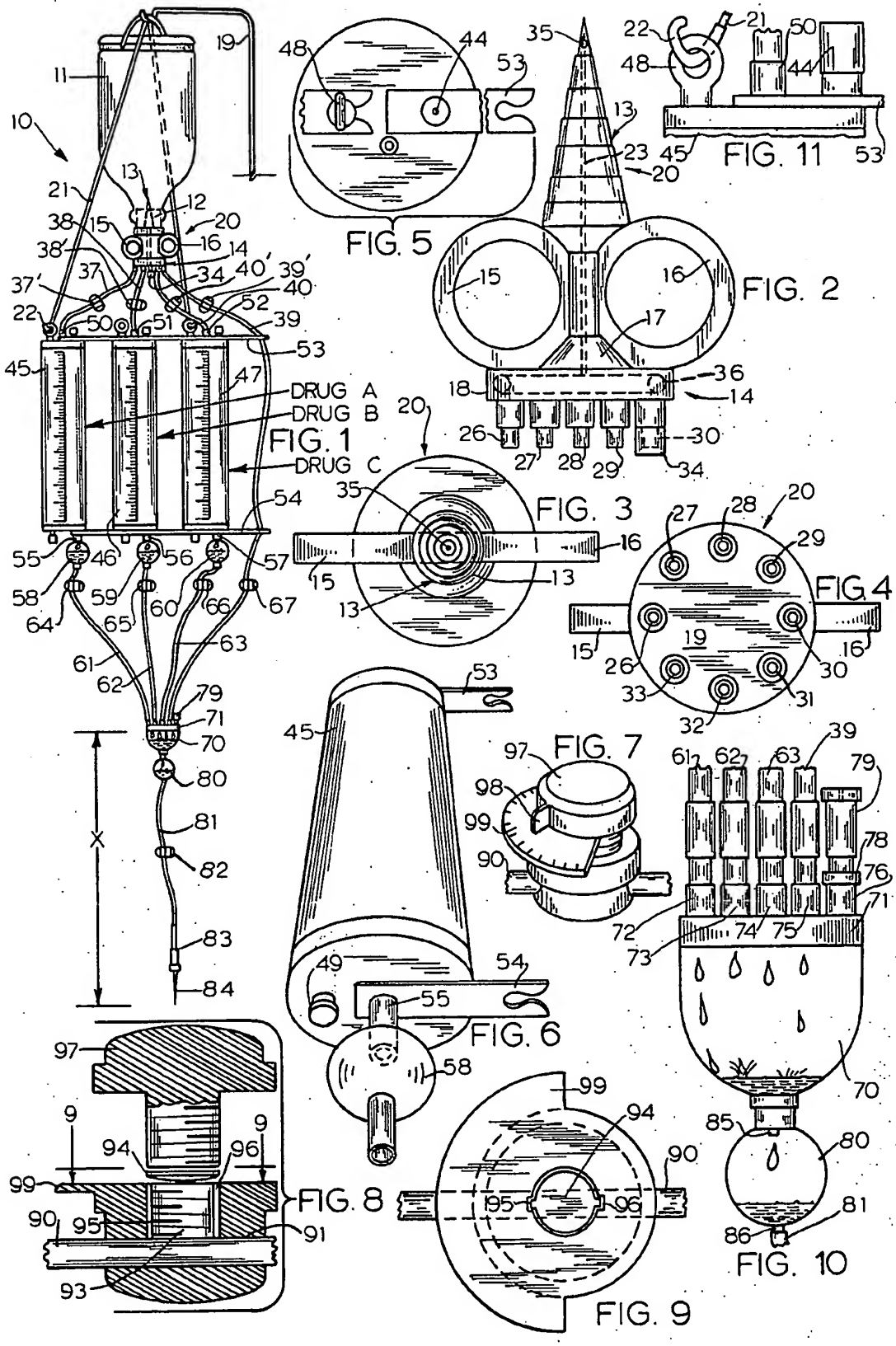
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—B. B. Olive

[57] **ABSTRACT**

An apparatus for intravenous administration of multiple medications of types which tend to be incompatible provides means for diluting the medications separately with a diluent drawn from a common diluent source and for combining the diluted medication at a site proximate to the point of venous entry in order to reduce the opportunity for the medications to mix externally of the body.

10 Claims, 11 Drawing Figures




DRUG A
DRUG B
DRUG C
FIG. 1
FIG. 2
FIG. 3
FIG. 4
FIG. 5
FIG. 6
FIG. 7
FIG. 8
FIG. 9
FIG. 10
FIG. 11

APPARATUS FOR LONG TERM INTRAVENOUS ADMINISTRATION OF DILUTED INCOMPATIBLE MULTIPLE MEDICATIONS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The apparatus of this invention is related to intravenous administration of medications and fluids and particularly to multiple administration of medications and fluids which have physio-chemical incompatibilities.

2. Description of the Prior Art

While vast forward steps have been made in recent years in the development of medications and fluids to be administered to patients, the mechanical art of administration has not kept pace with these scientific developments. The apparatus for administering such medications and fluids intraveneously in the patient, have led to a more or less standard type of infusion set which is comprised of a solution bottle having a stopper apertured for puncturing and venting, a spike or cap device which allows a tube to be connected to the bottle contents through puncturing the bottle stopper, the tube which connects the bottle to the needle, a drip chamber or indicator, and a means of flow control comprising a pinch clip or cock. When a plurality of fluids and medications are to be administered simultaneously, it has been necessary to use a separate needle, tubing and venipuncture for each solution, or to use one or more Y-tubes. Two, three and even four way stop cocks have been employed, and very frequently the flow from two or more fluids or medications, even though incompatible, have been combined and been given the opportunity to mix over a long time prior to entry into the body. Another system of administration is designed to permit the contents of two or more intravenous solution bottles to flow into a patient while all are connected together. Such a system allows an unlimited number of bottles to be connected in "series."

Today, fluids such as saline, dextrose and lactated fingers, to name a few, are administered by infusion using special equipment. The equipment is sterile, disposable and subject to stringent controls in the hospitals. An increasing hospital practice for the administration of medications is to combine them with such fluids. Many of these are life saving drugs and by their nature are administered intravenously quite often; in some cases, there is no other choice. Today, it is a very common practice for a physician to order three or more drugs to be administered simultaneously to the patient. Many of these drugs have chemical and physical incompatibilities and which is of special significance to the invention.

Numerous references are available concerning the critical problem of medication incompatibilities. The Norfolk General Hospital, Pharmacy Service, publication entitled "Intravenous Fluids, Incompatibility Guide" cites many such references and lists the following factors which may cause incompatibilities:

Preservative of Drug	Oxidation
Preservative in Diluent	Reduction
Buffering Agents	Photosensitization
Antioxidants	Inactivation
Vehicle	Order of Mixing
Changes in pH	Period of Standing
Molecular Complexation	Brand of Drug
Supersaturation	Neutralization
Change in Viscosity	Precipitation
Particle size distribution	Improper Dilution

There are a number of ways to handle the incompatibility problem, all of which are presently unsatisfactory. The common method is to add one drug to the basic fluid in a burrett device and infuse it over an hour, then add the second drug, etc., thus consuming an inordinate amount of nursing time. Physicians and nurses are often concerned with such matters as the Ph of a fluid or its chemical and physical incompatibilities. The majority of incompatibilities are kinetically slow in developing, which necessitates the use of small volumes of basic infusion fluid as a diluent in a burrette device in contrast to placing all of the drugs to be administered in the 8 hour period in one large volume container. In many United States hospitals, the pharmacy has developed an intravenous (I.V.) fluid admixture service. The I.V. drugs are reconstituted and/or packaged aseptically in suitable small volume containers to be added by the nurse to existing I.V. infusions. Another practice is to actually prepare the large volume I.V. infusion which contains the drugs in labeled containers which are delivered to the nurse for subsequent administration. With the hospital pharmacist becoming more involved in intravenous admixture preparation and monitoring, the need for more accurate and dependable systems of delivery for incompatible medications is of paramount importance.

SUMMARY OF THE INVENTION

This invention is an improvement on the equipment now in use for diluting, storing prior to administration, and administering of multiple medications and fluids where the same are for some reason incompatible in the sense previously discussed. A spike or piercing pin has integral finger grips and is adapted to be universal for insertion into the stopper, which is normally of rubber, of any of a number of diluent fluid bottle types. A manifold structure is made integral with the universal spike and functional engagement of the spike with the resilient stopper provides support for the integral spike-manifold structure. The manifold receives the fluid from the inserted spike and directs it out through a plurality of discharge ports and into a number of flexible intake tubes. Each intake tube transfers the fluid into a calibrated medication chamber or one or more tubes can bypass these chambers if so desired. The calibrated chambers act as infusion containers and are arranged so that they can be releasably secured together in a side-by-side relation. Once within the calibrated medication chamber, the fluid and a medication, previously placed in the respective chamber, mix and form a solution. Thus, each chamber acts as a means for diluting with a common fluid a particular medication and for keeping such diluted medication isolated from diluted medications in other chambers. A discharge tube discharges the fluid-medication solution from the base of each calibrated chamber. Each discharge tube, except for the bypass tubes, includes in its path an individual drip chamber and an individual regulator valve which allows for display and individual control of the rate of discharge of each respective solution. Thus, each fluid medication solution can be individually regulated.

A common drip chamber is located immediately adjacent the injection site and has a manifold head which connects to the discharge tubes including any bypass discharge tube. This last mentioned drip chamber thus allows for final mixing of all fluid-medication solutions and all bypassed fluid immediately prior to administration into the patient's vein. A final regulator valve is situated in the tube leading to the injection site and provides for control of the rate of discharge of the final solution. This last mentioned tube is connected to a conventional needle adaptor which in turn mounts a suitable needle for insertion into the vein of the patient.

In summary, the apparatus of the invention provides a multiple drug and fluid infusion system wherein incompatibilities are kept to a minimum since contact time of drugs is kept at a minimum, when in a mixed state external of the body. Several other improvements and advantages over presently existing devices are: (a) additional drugs can be added to the infusion set without disruption of previous infusion parameters, (b) rates of infusion can be controlled independently of each other, (c) when drugs are discontinued by the physician, the remaining drugs can be administered without waste, and (d) drugs in separate chambers or burrettes will not mix.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevation view of an assembly of apparatus incorporating the present invention.

FIG. 2 is an enlarged elevation view of the integral universal spike-manifold employed by the invention.

FIG. 3 is a plan view of the integral universal spike-manifold employed by the invention.

FIG. 4 is a bottom view of the integral universal spike-manifold.

FIG. 5 is a plan view on a reduced scale of one of the calibrated solution chambers.

FIG. 6 is a perspective view of a calibrated solution chamber and showing a drip chamber located adjacent the base thereof.

FIG. 7 is a perspective view of a regulator valve employed with the invention for controlling rate of flow.

FIG. 8 is a partial section, enlarged exploded elevation view of the regulator valve.

FIG. 9 is a plan view taken along line 9—9 of FIG. 8.

FIG. 10 is an enlarged elevation view of the solution mixing chamber and associated drip chamber.

FIG. 11 is a partial elevation view of the top portion of one of the calibrated solution chambers.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings in detail wherein like numbers pertain to like parts, reference is first made to FIG. 1 wherein the entire apparatus of the preferred embodiment of the invention is shown.

The apparatus of the invention is directed to distributing a common diluent to a plurality of diffusion chambers, allowing otherwise incompatible medications to combine with the fluid mix therein and then directing all of the combined medications to the site of injection. Such apparatus is generally designated as **10**. A standard, sterile fluid filled container or bottle **11**, of the type capable of being suspended from support **19** while inverted has a rubber or like resilient stopper **12** sealing its top and which is conventionally provided with a preformed puncturing aperture and vent aperture. The spike-manifold structure **20** has a universal

spike or piercing pin **13** which is adapted to be inserted into the center of stopper **12** of bottle **11**. Spike **13** is preferably of a stepped, tapered design as illustrated which makes it adaptable for use with various sizes of puncturing apertures and thus with practically all standard bottles **11**. A housing portion **14** of spike **13** has made integral therewith finger grip members **15, 16**. Base **17** of housing **14** flares outwardly and forms a manifold **18**. Manifold **18** has several discharge ports **26** through **33** enabling the fluid from bottle **11** to be distributed to a plurality of diffusion containers as later described. An opening **35** in the tip of spike **13** connects to a central bore **23** which extends through spike **13** and communicates with a cavity **36** in manifold **18**. Ports **26** through **33** have, when not in use, covering caps **34** (FIG. 2) which close off manifold **18** to prevent flow of fluid therefrom and to prevent entry of germs, and the like.

Flexible conduits or tubes **37, 38, 39, 40**, only four being shown for purpose of illustration, are preferably adapted at one end with suitable couplers for quick coupling to any of discharge ports **26** through **35** and at the other end for quick coupling to any of calibrated containers **45, 46, 47** through their respective intake ports **50, 51, 52**. Also, a conduit can be arranged to by-pass the calibrated medication chambers **45, 46, 47** as does conduit **39**. Such an arrangement allows a controlled quantity of diluent to be added to the composite mix of diluted medications in chamber **70** immediately prior to injection. Tubes **37, 38, 39, 40** are preferably provided with conventional pinch valves **37', 38', 39'** and **40'**. The fluid filled containers may average about 160 grams each in weight. Support for containers **45, 46**, and **47** is provided. In the embodiment illustrated, a flexible wire **21** has a hook **22** which engages one of the eyelet knobs **48** and wire **21** is otherwise passed through other respective eyelets provided by eyelet knobs **48**, as best shown in FIGS. 1 and 11, and appropriately tied.

Containers **45, 46, 47** are intended to serve as containers for holding three separate medications, e.g., medications A, B and C and for allowing these to be separately diluted with the appropriate diluent from bottle **11**. To facilitate the coordination of the separate mixing operations, each container is provided with top and bottom holders **53, 54** having resilient slotted ends as shown which snap-fit to corresponding eyelet knobs **48** (FIG. 5) and knobs **49** (FIG. 6). Holders **53, 54**, as illustrated, comprise thin bars which are glued, welded or otherwise secured to the respective containers **45, 46, 47**. Eyelet knobs **48** serve both to receive wire **21** for support purposes and as a means for securement to the holders **53, 54**. Containers **45, 46, 47** are further provided with appropriate air vents **44** and with respective discharge ports **55, 56, 57**, from which the respective mixed medication diluent solutions are allowed to exit. Each discharge port **55, 56, 57** connects to respective drip chambers **58, 59, 60**, which in turn connect to respective tubes **61, 62, 63** having respective regulator valves **64, 65, 66** which provide for individual control of rate of discharge of each medication-diluent solution. While not shown, bypass line **39** may also include a drip chamber. Bypass line **39** also has an individual regulator valve **67** which controls the rate of direct flow of fluid from bottle **11** into a common drip, mixing chamber **70**, which is located immediately adjacent, or as close as practical, to the injection site.

A manifold head portion 71 in chamber 70 receives the various medication-diluent solutions through inlet ports 72–75 and directs them to chamber 70 proper to be mixed with whatever amount of diluent is allowed to flow through tube 39. Conduits 61, 62, 63 and 39 preferably utilize quick connect couplings and any unused inlet port, e.g., inlet port 76, can be closed off by using a suitable top 78 which keeps mixing chamber 70 free of contamination. An air filter 79 (FIG. 1) is placed on one of the manifold head inlet ports as required. It should be noted that chamber 70 allows for the first mixing of all the medication-drug solutions and immediately prior to administration into the patient's vein. A common drip chamber 80 is located immediately adjacent and below mixing chamber 70 and a short conduit 81 extends from chamber 80 to provide a final path for the mixed solutions to the needle insertion point. For purposes of being able to control the flow of the mixed solutions, it is noted that the exhaust port 85 for chamber 70 should be sufficiently larger than the exhaust port 86 of the drip chamber 80 to allow a visible accumulation of liquid in drip chamber 80.

Flow through conduit 81 to the needle site is controlled by a final regulator valve 82. Conduit 81 connects to a needle adapted 83 which in turn mounts a suitable needle 84 for insertion into the vein of the patient. With the described invention system, distance X (FIG. 1) should and can be kept minimal in order to minimize the described incompatibility effect.

Referring to FIG. 1, an application of the present invention apparatus 10 will be described. It is assumed that a doctor needs to administer given quantities of three drugs A, B and C which are placed in respective containers 45, 46 and 47 and are to be mixed with a basic fluid or diluent D. However, it is assumed that drug A is not compatible with drug B and drug C is not compatible with either or the combination of drugs A and B. By compatibility is meant chemical and physical compatibility external of the body as related to any of the recognized compatibility factors previously mentioned or other factors of the same effect. Once in the vein, drugs will normally distribute in the body in approximately 15 seconds provided adequate circulation exists; therefore, the primary problem dealt with by the invention concerns compatibility external of the body.

In the assumed example, a suitable diluent filled bottle 11 is suspended and supported, as illustrated. The drug holding calibrated chambers 45, 46, 47 are snap-fitted together by the respective connectors 53, 54 engaging the respective top eyelet knobs 48 and bottom knobs 49 and are suspended below bottle 11 in a laterally aligned and spaced position. Conduits 37, 38, 40 are respectively secured on one side to chambers 45, 46, 47 and on the other side to discharge ports 28, 29, 30 of manifold 18. Spike portion 13 is inserted into rubber stopper 12 of bottle 11 and bypass line 39 is connected to manifold 18 at port 32. Drip chambers 58, 59, 60; conduits 61, 62, 63 and 39 are connected to the respective inlet ports of manifold head portion 71 of common drip, mixing chamber 70. Now drip chamber 80, conduit 81, valve 82, needle adaptor 83 and needle 84 are assembled.

As fluid from bottle 11 drips into chambers 45, 46, 47, a solution of drug and fluid is made in each chamber. As each medication-diluent solution leaves its respective chamber and passes into its respective drip chamber, the solution flows therefrom and its rate of flow is independently adjusted by the respective valves 64, 65, 66 with flow through bypass line 39 being controlled by valve 67. Chamber 70 provides the first inter-drug-diluent solution mixing point for each of the individual solutions prior to administration to the patient. Once needle 84 is inserted into the patient's vein, the system can be started by adjusting to the desired administration rate by setting the appropriate regulator valves. The mixed solution thus travels only over distance "X." In a typical bedside infusion system according to the invention, the distance "X" can be made as short as 72 inches and the approximate time of flow of the mixed drug-diluent solution from chamber 70 to needle 84 can be as low as about 10 ml./hour Thus, opportunity for external incompatible mixing is minimized.

While a wide variety of pinch valves are available, the type pinch valve illustrated in FIGS. 7–9 has been found particularly useful to the invention for purposes of valves 64–67 and 82. In this regard, it will be noticed that the illustrated tube 90 is received by one passage 91 which is perpendicular to the threaded passage 92 and in which the dished plate 94 is loosely guided in slots 95, 96. As threaded knob 97 is turned, plate 94 pinches tube 90 an amount which can be controlled by reference to index point 98 and index plate 99.

The apparatus of the invention thus provides a multiple drug and fluid infusion system wherein incompatibilities are kept to a minimum since contact time of drugs is kept at a minimum. Rates of infusion of the different drugs can be controlled independently of each other. Also, additional drugs can be added to the infusion set without disrupting the previous infusion parameters. If a physician should want to discontinue a particular drug, the remaining drugs can be administered without disturbance.

It will also be appreciated by those skilled in the art that the apparatus described is not limited to the disclosed administration but is also useful in connection with administration of blood, serums, and the like, where there is a fluid incompatibility problem of the kind described. While the invention is shown in connection with three individual drugs, it will be understood that it can be utilized with a single drug or with any number of drugs as desired.

Of particular advantage is the integral spike-manifold structure. The pointed spike body is effectively made up of sections of increasing diameter which make the spike universal for various sized puncturing apertures and thus for resilient bottle stoppers. Also, the tapered, stepped conical formation of the spike enables the spike to be frictionally engaged in such types of stoppers and to provide support for the overall spike-manifold structure. The manifold with its plural discharge ports which connect to the aperture and central passage of the spike insure ease of distribution of the diluent to any comparable number of containers.

Also of advantage to the invention is the mixing and sight assembly composed of mixing chamber 70 and drip chamber 80. This assembly allows a plurality of separate diluent-medication solutions to be received through a manifold and to combine, for the flow rate of each solution to be observed as it enters the chamber from the manifold prior to mixing and allows for all the solutions to leave through a single exhaust port and the flow rate of the combined solutions to be separately observed. Use of the mentioned air filter 79 on chamber 70 when suitably sized prevents pressurization and aids in preventing the situation of fluid from one con-

tainer going into chamber 70 and then tending to flow to another container rather than out of chamber 70.

What is claimed is:

1. An apparatus for diluting, combining, and intravenously injecting a plurality of potentially incompatible substances including medications comprising, in combination:

a. a bottle having a penetrable vented stopper and containing a supply of a selected diluent to be withdrawn through the stopper with the bottle inverted;

b. an integral spike-manifold structure adapted for placement below said bottle and providing a spike adapted to penetrate said stopper and provide a fluid passage therethrough and communicating with said passage a manifold providing a plurality of discharge ports enabling said diluent to be withdrawn from said bottle through said spike and made available for discharge through each of said ports, said manifold structure having a finger grip formation formed integral therewith and adapted to receive an operator's fingers for installing said spike;

c. a plural configuration of tubes, sight chambers, valves and vertically disposed calibrated transparent containers supported below said bottle and spike-manifold structure and providing means whereby various incompatible substances such as medications may be isolated in measured amounts and diluted with the same said diluent while remaining in isolation from each other and at individually controlled rates of flow therethrough, each container having a top inlet port, a tube connection between such inlet port and a respective said manifold discharge port, a bottom outlet port and a bottom tube connected thereto and leading downward therefrom, each bottom tube having in its path a sight chamber and a regulator valve for individually regulating the flow therethrough;

d. a mixing-sight chamber having on one upper side a plurality of inlets connected respectively to said bottom tubes for individually receiving and then combining the individually mixed medication-diluent fluids discharged by said containers and on an opposite lower side a discharge port; and

e. a fluid injection assembly including a tube having in its path a further sight chamber and regulator valve and said assembly being connected on one end to said mixing-sight chamber discharge port and on the opposite end to a needle for vein injection.

2. An apparatus as claimed in claim 1 wherein said spike-manifold structure finger grip formations inlcudes a pair of ring members formed integral therewith and adapted to receive an operator's fingers for installing said spike.

3. An apparatus as claimed in claim 1 including an auxiliary tube connected between a said manifold discharge port and a said mixing-sight chamber inlet and having a regulator valve associated therewith thereby enabling predetermined quantities of said diluent to bypass all of said containers and to initially mix with the contents thereof in said mixing-sight chamber.

4. An apparatus as claimed in claim 1 wherein at least selected ones of said regulator valves include means for effectively pinching the respective said tubes and index means by which the amount of such pinching can be visually observed.

5. An apparatus as claimed in claim 4 wherein each said selected ones of said valves comprise a body member mounting an index plate, a first aperture for receiving the respective tube to be regulated, a second threaded aperture communicating with and axially oriented perpendicular to the first aperture, and having a sliding plate member therein, and a threaded screw member received by said second aperture and adapted upon being turned to press said plate member against the respective tube to effect said pinching and having an appended index enabling said turning to be referenced to said index plate.

6. An apparatus as claimed in claim 1 including connector means on said containers enabling them to be detachably secured together side by side and comprising a pair of opposed connector bars respectively secured on one end to the tip and bottom of each said container and having the opposite end provided with an open-ended slot, and knob members located on said container top and bottom and adapted to be detachably received in said slots to effect said securement.

7. An apparatus as claimed in claim 1 wherein said spike is conical-shaped and the body thereof is formed in portions of increasing diameter and said passage includes an aperture at an outer pointed end of said spike and a channel communicating therewith and extending lengthwise and internally of said body between said manifold and said aperture.

8. An apparatus as claimed in claim 1 including detachably connector means having respective mating portions secured to the respective said containers whereby a plurality of such containers may be secured together in a side-by-side relation.

9. An apparatus as claimed in claim 1 wherein said mixing sight chamber includes an air filter sized to relieve any tendency for said mixing sight chamber to serve as a flow path between said containers.

10. An integral spike-manifold structure for distributing fluid from a bottle having a penetrable vented stopper and a fluid to be withdrawn through the stopper with the bottle inverted, comprising in combination:

a. a conical-shaped spike portion having a body formed with a pointed end, consecutive body sections of increasing diameter, an aperture in said end and an internal central passage extending through said body;

b. a pair of ring-shaped members appended to said body and enabling finger grasping of said structure; and

c. a manifold portion providing a plurality of discharge ports and internal passages connecting said ports to said body passage enabling fluid from said bottle to be withdrawn through said aperture and discharged through each of said ports.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,941,126 Dated March 2, 1976

Inventor(s) Joseph W. Dietrich et al

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Col. 1, line 18,"intraveneously" should be --intravenously--.

In Col. 5, line 25,"adapted" should be --adaptor--.

In Col. 6, line 13,a period should be placed after "hour".

In Col. 8, line 24, "tip" should be --top--.

Signed and Sealed this

Twentieth Day of July 1976

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks

US005318515A

United States Patent [19]

Wilk

[11] Patent Number: 5,318,515

[45] Date f Patent: Jun. 7, 1994

[54] **INTRAVENOUS FLOW REGULATOR DEVICE AND ASSOCIATED METHOD**

[76] Inventor: Peter J. Wilk, 185 W. End Ave., New York, N.Y. 10023

[21] Appl. No.: 931,260

[22] Filed: Aug. 17, 1992

[51] Int. Cl.[5] A61M 5/175

[52] U.S. Cl. 604/30; 604/186; 604/246; 604/250

[58] Field of Search 604/186, 65-67, 604/131, 80, 81, 247, 250, 246, 30

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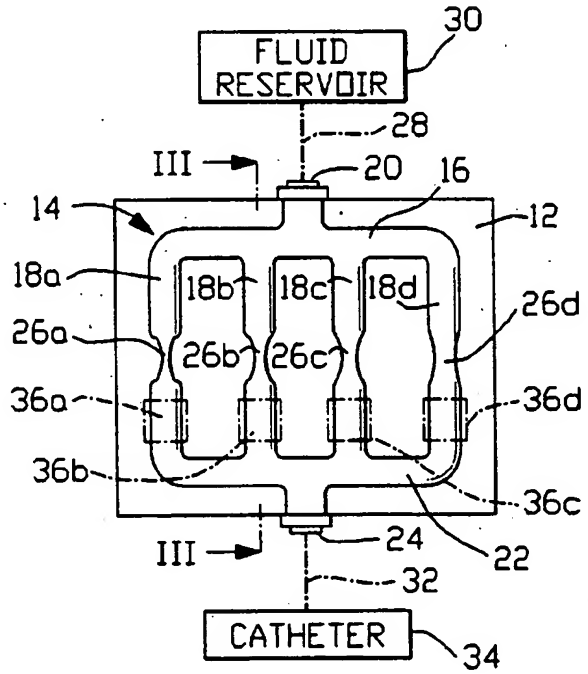
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—R. Neil Sudol; Henry D. Coleman

[57] ABSTRACT

A device for regulating fluid flow in an intravenous line comprises a housing and a flow path system in the housing for defining a plurality of separate flow paths having respective predetermined characteristic flow rates. The housing has an input port connectable to an intravenous line segment extending from an intravenous fluid supply and also has an output port connectable to an intravenous line segment extending to a catheter. The device additionally comprises a selector mounted to the housing and in contact with the flow path system for selectively opening the flow paths to connect the output port to the input port, thereby controlling the amount of fluid or solution flowing through the output intravenous line to a patient.

15 Claims, 2 Drawing Sheets



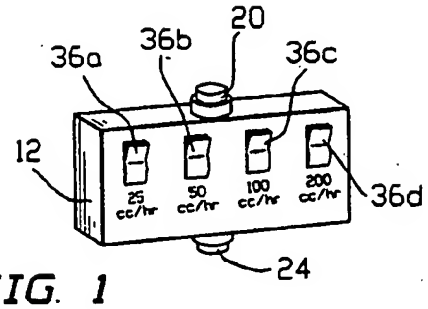


FIG. 1

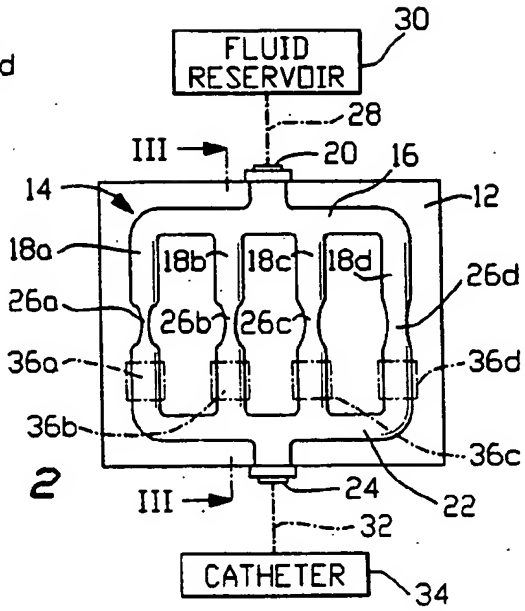


FIG. 2

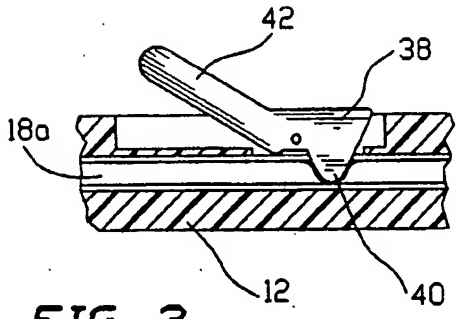


FIG. 3

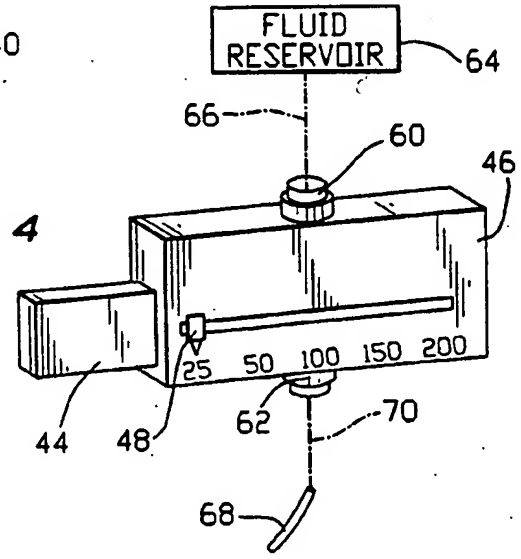


FIG. 4

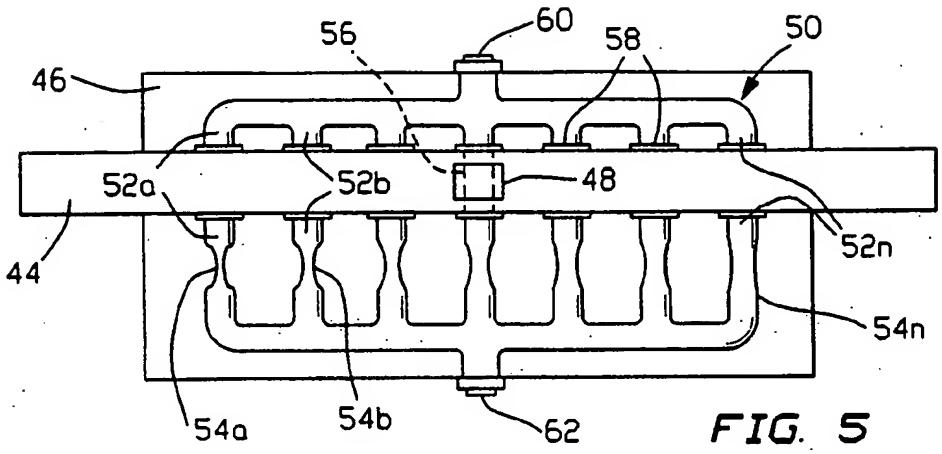


FIG. 5

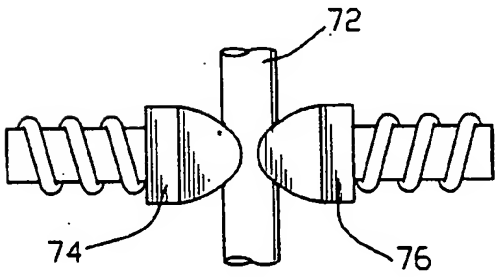


FIG. 6

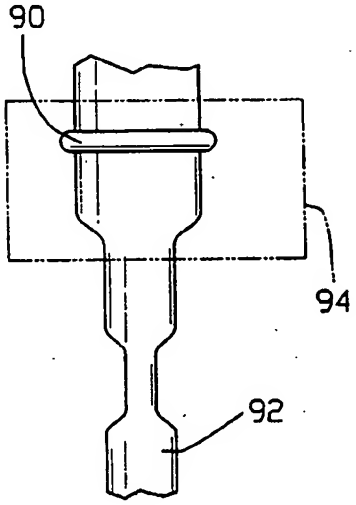


FIG. 8

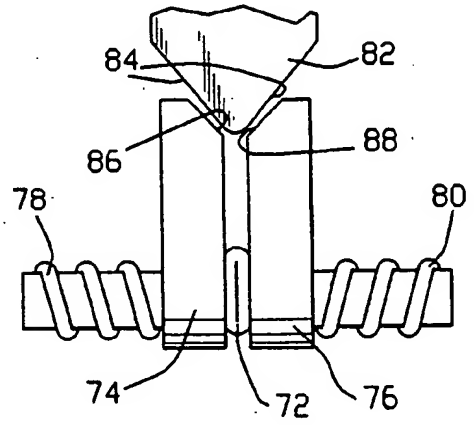


FIG. 7

INTRAVENOUS FLOW REGULATOR DEVICE AND ASSOCIATED METHOD

BACKGROUND OF THE INVENTION

This invention relates to an intravenous fluid supply system. More particularly, this invention relates to a device for regulating the rate of fluid flow through an intravenous line into a patient. This invention also relates to an associated method for controlling the rate of intravenous feeding.

It is important that intravenous solutions are fed to patients at prescribed rates. A rate that is too high or too low can mean disaster to many patients, delicate conditions.

Generally, the rate of intravenous fluid flow is set by constricting a flexible tube extending from an elevated intravenous solution bag to a catheter in the patient. More specifically, the constriction is accomplished by pushing a valve member to pinch the flexible intravenous tube between the valve member and a tapered ramp extending through a housing. To set a desired rate, one views a drip chamber upstream of the valve member. The valve is adjusted until a prescribed number of drips per time unit is counted at the drip chamber.

This conventional rate setting method is inaccurate and prone to error. Nurses frequently do not have the opportunity to accurately monitor the flow rate prior to a final selection.

OBJECTS OF THE INVENTION

An object of the present invention is to provide an improved method for setting an intravenous flow rate.

Another object of the present invention is to provide such a method which results in increased accuracy.

Another, more particular, object of the present invention is to provide such a method which is easy and quick to implement.

An associated object of the present invention is to provide a device connectable in an intravenous flow line for facilitating the setting of flow rate.

Yet another particular object of the present invention is to provide an intravenous flow rate regulator which is inexpensive to manufacture.

These and other objects of the invention will be apparent from the descriptions and illustrations provided herein.

SUMMARY OF THE INVENTION

A device for regulating fluid flow in an intravenous line comprises, in accordance with one conceptualization of the present invention, a housing and a flow path system in the housing for defining a plurality of separate flow paths having respective predetermined characteristic flow rates. The housing has an input port connectable to an intravenous line segment extending from an intravenous fluid supply and also has an output port connectable to an intravenous line segment extending to a catheter. The device additionally comprises a selector mounted to the housing and in contact with the flow path system for selectively opening the flow paths to connect the output port to the input port, thereby controlling the amount of fluid or solution flowing through the output intravenous line to a patient.

Pursuant to one embodiment of the present invention, the flow path system includes a plurality of resilient tubes connected in parallel to one another in a manifold, the tubes having respective cross-sectional areas. In that event, the selector may include a blocking mechanism for collapsing the tubes to close the tubes. More specifically, The blocking mechanism includes parts of a plurality of toggle switches in contact with respective tubes of the flow path system. Preferably, the cross-sectional areas of the tubes of the flow path system are different from each other.

Pursuant to another embodiment of the present invention, the flow path system includes a plurality of divided tubes each associated with a respective one of the flow paths, the characteristic flow rates of each divided tube being different from the characteristic flow rates of the other tubes in the flow path system. The selector then includes means for selectively permitting fluid flow through only one of the divided tubes. More specifically, upon selection and implementation of a desired flow rate in an intravenous line, all of the tubes except one are blocked, the opened tube being aligned with a bridging duct with connects downstream and upstream parts of the tube. The bridging duct may be provided in a sliding member which automatically blocks all tubes other than the tube having the selected flow rate.

Pursuant to a further embodiment of the present invention, the selector includes a plurality of spring loaded valves associated with respective flow paths, the selector further including an actuator movably mounted to the housing for selectively opening the valves.

In yet another embodiment of the present invention, the selector includes a plurality of frangible seals associated with respective flow paths, the selector further including an actuator movably mounted to the housing for selectively breaking the seals.

Pursuant to one feature of the present invention, the characteristic flow rates of the different flow paths of the flow path system are different from each other. Alternatively, the characteristic flow rates are uniform, the selector including means for selectively opening a plurality of the flow paths simultaneously. Where the characteristic flow rates are different, multiple flow paths of the flow path system may be connected between the input port and the output port, thereby providing a greater selection of possible flow rates.

Pursuant to another feature of the present invention, indicators are provided on the housing for indicating different flow rates at different operative positions of the selector.

A method for use in intravenous feeding comprises, in accordance with the present invention, the steps of (a) inserting an intravenous catheter into a patient, (b) connecting an intravenous supply to an inlet side of a flow regulator, (c) opening at least one of plurality of possible flow paths through the flow regulator to connect the inlet side of the flow regulator to the outlet side thereof, and (d) connecting the catheter to an outlet side of the flow regulator. The flow paths have predetermined characteristic flow rates which may be the same or different from each other.

According to another feature of the present invention, the step of opening one or more flow paths includes the step of pivoting a toggle switch to unclamp a flexible tube.

According to an alternative feature of the present invention, the step of opening one or more fluid flow paths includes the step of shifting a slider member in the flow regulator to connect an input tube to an output tube.

According to another alternative feature of the present invention, the step of opening one or more fluid flow paths includes the step of opening one of a plurality of distinct valve elements.

According to yet another alternative feature of the present invention, the step of opening one or more fluid flow paths includes the step of breaking one of a plurality of distinct seal elements.

A device for regulating fluid flow in an intravenous line comprises, in accordance with another conceptualization of the present invention, a housing, a flow path system in the housing for defining a plurality of separate flow paths having respective predetermined characteristic flow rates, an input port on the housing connectable to an intravenous line extending from an intravenous fluid supply, and an output port on the housing connectable to an intravenous line extending to a catheter. The input port communicates with the flow path system on an inlet side thereof, while the output port communicates with the flow path system on an outlet side thereof. A closure element or elements are mounted to the housing and in contact with the flow path system for closing the flow paths and thereby blocking fluid flow therethrough, and a selector or selectors are mounted to the housing for selectively releasing the closure elements to selectively open the flow paths to connect the output port to the input port.

Pursuant to another feature of the present invention, the flow path system includes a plurality of resilient tubes connected in parallel to one another in a manifold, the tubes having respective cross-sectional areas. The closure elements serve to block or collapse the tubes and may include lever elements of a plurality of toggle switches, the lever elements being in contact with respective resilient tubes.

The present invention provides an improved method for setting an intravenous flow rate. The method provides for increased accuracy and is easy and quick to implement.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a schematic isometric view of an intravenous flow regulator device in accordance with the present invention.

FIG. 2 is a diagram illustrating components of the flow regulator device of FIG. 1.

FIG. 3 is a partial cross-sectional view taken along line III—III in FIG. 2.

FIG. 4 is a schematic isometric view of another intravenous flow regulator device in accordance with the present invention.

FIG. 5 is a diagram illustrating components of the flow regulator device of FIG. 4.

FIG. 6 is a schematic partial top view of flow control components of yet another flow regulator device in accordance with the present invention.

FIG. 7 is a side elevational view of the flow control components of FIG. 6.

FIG. 8 is a schematic partial top view of flow control components of yet a further flow regulator device in accordance with the present invention.

DETAILED DESCRIPTION

As illustrated in FIGS. 1 and 2, a device for regulating fluid flow in an intravenous line comprises a housing 12 and a flow path system 14 in the housing. Flow path system 14 includes an input manifold 16 which connects a plurality of resilient or flexible tubes 18*a*, 18*b*, 18*c*, 18*d* to an input port 20 and an output manifold 22 which connects tubes 18*a*, 18*b*, 18*c*, 18*d* to an output port 24. Tubes 18*a*, 18*b*, 18*c*, 18*d* define respective separate flow paths having respective predetermined characteristic flow rates. More particularly, tubes 18*a*, 18*b*, 18*c*, 18*d* incorporate narrowed sections 26*a*, 26*b*, 26*c*, 26*d* of differing cross-sectional areas which present different flow resistances and therefore give rise to respective different flow rates. Fluid flows through individual tubes 18*a*, 18*b*, 18*c*, 18*d* at respective rates, for example, of 25 cc/hr, 50 cc/hr, 100 cc/hr, and 200 cc/hr.

Input port 20 is connectable to an intravenous line segment 28 extending from an intravenous fluid supply 30, while output port 24 is connectable to an intravenous line segment 32 extending to a catheter 34. A plurality of selectors in the form of toggle switches or buttons 36*a*, 36*b*, 36*c*, 36*d* are mounted to housing 12 and are in contact with respective tubes 18*a*, 18*b*, 18*c*, 18*d* of flow path system 14 for selectively opening the flow paths thereof to connect output port 24 to input port 20. Toggle switches 36*a*, 36*b*, 36*c*, and 36*d* enable a user to control amount of fluid or solution flowing through intravenous line segment 32 to a patient.

As illustrated in FIG. 3, toggle switches 36*a*, 36*b*, 36*c*, 36*d* each include a first lever 38 provided with a projection 40 which is engageable with a respective tube 18*a*, 18*b*, 18*c*, 18*d* in an "off" or closed position of the switch to clamp or block the respective tube. Prior to use, every toggle switch 36*a*, 36*b*, 36*c*, 36*d* is set in a closed configuration, as shown in FIG. 1. Each toggle switch 36*a*, 36*b*, 36*c*, 36*d* further includes a second lever 42 which is pressed in order to open the respective tube or fluid flow path 18*a*, 18*b*, 18*c*, 18*d*.

In using the intravenous flow regulator of FIGS. 1 and 2, catheter 34 is inserted into a vein or artery of a patient. Intravenous fluid reservoir or bag 30 is connected to input port 20 via intravenous line segment 28, while intravenous line segment 32 is connected to output port 24. Catheter 34 is coupled to output port 24 via line segment 32. At least one tube or flow path 18*a*, 18*b*, 18*c*, or 18*d* through the flow regulator is then opened by pushing the "on" lever 42 of the respective toggle switch 36*a*, 36*b*, 36*c*, 36*d*. Of course, the desired flow path opened and the output line segment 32 is flushed preferably prior to connection thereof to catheter 34, to clear the line of air bubbles.

It is to be noted that flow path system 14 is designed so that a plurality of toggle switches 36*a*, 36*b*, 36*c*, 36*d* may be actuated to open a plurality of tubes or fluid flow paths 18*a*, 18*b*, 18*c*, 18*d*, thereby providing a greater range of possible flow rates. For example, toggle switches 36*a*, 36*b*, and 36*c* may be pressed to open tubes 18*a*, 18*b*, and 18*c*, thereby setting a flow rate of 175 cc/hr, equal to the combined flow rates of the three tubes.

As illustrated in FIGS. 4 and 5, in another intravenous flow regulator, a slider member 44 is slidably disposed in a housing 46 for setting or selecting a desired flow rate. Slider member is provided with a pusher 48 which is used to shift the slider to select a desired flow rate and which additionally serves as a pointer indicating a selected fluid flow rate. Housing 46 carries a flow path system 50 including a plurality of divided tubes 52*a*, 52*b*, . . . 52*n* each defining a respective flow path having a respective characteristic flow rate different from the characteristic flow rates of the other tubes in flow path system 50. The different flow rates may be achieved, for example, by providing tubes 52*a*, 52*b* . . .

52*n* with segments 54*a*, 54*b*, . . . 54*n* of reduced cross-section and different resistances to fluid flow.

Slider member 44 serves for selectively permitting fluid flow through only one of divided tubes 52*a*, 52*b* . . . 52*n*. To that end, slider member 44 is provided with a single duct or channel 56 which is alignable with any one of tubes 52*a*, 52*b* . . . 52*n*, depending on the position of slider member 44. Slider member 44 serves to block fluid flow through the other tubes 52*a*, 52*b* . . . 52*n*. Tubes 52*a*, 52*b* . . . 52*n* are provided with sealing rings 58 which engage slider member 44 to effectuate a fluid tight seal therewith.

As illustrated in FIG. 5, tubes 52*a*, 52*b* . . . 52*n* are connected on an inlet side to an input port 60 on housing 46 and on an outlet side to an output port 62 on the housing. As illustrated in FIG. 4, input port 60 is connectable to an intravenous fluid reservoir or supply 64 via an inlet line segment 66 and to an intravenous catheter 68 via an outlet line segment 70.

Upon selection and implementation of a desired flow rate in the intravenous line extending from supply 64 to catheter 68, all tubes 52*a*, 52*b* . . . 52*n* except one are blocked by slider member 44. The opened tube is aligned with bridging duct 56 with connects downstream and upstream parts of that tube, as indicated in FIG. 5

It is to be noted that housing 46 may enclose slider member 44 in its entirety, which particularly enhances sterility.

The intravenous flow regulator of FIGS. 4 and 5 is used in a manner similar to the use of the flow regulator of FIGS. 1 and 2. In the embodiment of FIGS. 4 and 5, only one tube 52*a*, 52*b* . . . 52*n* can be opened at any one time. Therefore, many tubes 52*a*, 52*b* . . . 52*n* must be provided if it is desired to increase the range of selectable flow rates.

As depicted in FIGS. 6 and 7, another intravenous flow rate regulator may be provided with a plurality of tubes 72 (only one shown) connected in parallel to one another by a manifold (not shown). Each tube 72 is closed or blocked by one or two clamping members 74 and 76 slidably mounted to a housing (not illustrated) and biased into contact with tube 72 by respective springs 78 and 80. Each tube 72 represents a characteristic flow rate different from the flow rates of the other tubes. Clamping members 74 and 76 are spring loaded valves associated with respective flow paths.

In the flow regulator embodiment of FIGS. 6 and 7, a selector in the form of a spring loaded button 82 is slidably mounted to the housing. Upon a sliding of the button to the desired tube 72, button 82 is pressed so that camming surfaces 84 thereon cam against camming surfaces 86 and 88 of clamping members 74 and 76, thereby separating the clamping members in opposition to the closure forces exerted by springs 78 and 80 and opening the respective fluid flow tube 72. Button 82 may be provided with a detent or latch (not illustrated) for securing the button to the housing upon an actuation of the button.

In an embodiment of a flow regulator depicted in part in FIG. 8, a selector mechanism includes a plurality of frangible seals 90 (only one shown) associated with respective tubular flow paths 92 (only one shown). The selector mechanism further including an actuator 94 movably mounted to a housing (not shown) for selectively breaking the seals.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are profferred by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A device for regulating fluid flow in an intravenous line, comprising:
   - a housing;
   - flow path means in said housing for defining a plurality of separate flow paths having respective predetermined characteristic flow rates different from each other, said flow path means including a plurality of resilient tubes connected in parallel to one another in a manifold, said tubes having respective cross-sectional areas different in size from each other;
   - an input port on said housing connectable to an intravenous line extending form an intravenous fluid supply;
   - an output port on said housing connectable to an intravenous line extending to a catheter; and
   - selector means mounted to said housing and in contact with said flow path means for selectively opening said flow paths to connect said output port to said input port.

2. The device defined in claim 1 wherein said selector means includes blocking mean for collapsing said tubes to close same.

3. The device defined in claim 2 wherein said blocking means includes a plurality of toggle switches each in contact with a respective one of said tubes.

4. The device defined in claim 1 wherein said selector means includes means for selectively permitting fluid flow through only one of said tubes.

5. The device defined in claim 1 wherein said selector means includes a plurality of spring loaded valves associated with respective ones of said flow paths, said selector means further comprising actuator means movably mounted to said housing for selectively opening said valves.

6. The device defined in claim 1 wherein said selector means includes means for selectively opening a plurality of said flow paths simultaneously.

7. The device defined in claim 1, further comprising indicator means on said housing for indicating different flow rates at different operative positions of said selector means.

8. A method for use in intravenous feeding, comprising the steps of:
   - inserting an intravenous catheter into a patient;
   - connecting an intravenous supply to an inlet side of a flow regulator including a plurality of flexible tubes each deformably collapsed at a point along the respective tube;
   - deformably opening at least one of said flexible tubes to open at least one of plurality of corresponding flow paths through said flow regulator to connect the inlet side of the flow regulator to the outlet side thereof, said flow paths having respective predetermined characteristic flow rates different from each other; and
   - connecting said catheter to an outlet side of said flow regulator.

9. The device defined in claim 8 wherein said step of opening includes the step of pivoting a toggle switch to unclamp a flexible tube.

10. The device defined in claim 8 wherein said step of opening includes the step of opening one of a plurality of distinct valve elements.

11. A device for regulating fluid flow in an intravenous line, comprising:

a housing;

flow path means in said housing for defining a plurality of separate flow paths having respective predetermined characteristic flow rates different from each other, said flow path means including a plurality of resilient tubes connected in parallel to one another in a manifold, said tubes having respective cross-sectional areas different in size from each other;

an input port on said housing connectable to an intravenous line extending form an intravenous fluid supply, said input port communicating with said flow path means on an inlet side thereof;

an output port on said housing connectable to an intravenous line extending to a catheter, said output port communicating with said flow path means on an outlet side thereof;

closure means mounted to said housing and in contact with said flow path means for closing said flow paths and thereby blocking fluid flow therethrough; and

selector means mounted to said housing for selectively releasing said closure means to selectively open said flow paths to connect said output port to said input port.

12. The device defined in claim 11 wherein said closure means includes blocking means for collapsing said tubes to close same.

13. The device defined in claim 12 wherein said blocking means includes lever elements of a plurality of toggle switches, said lever elements being in contact with respective ones of said tubes.

14. The device defined in claim 11 wherein said characteristic flow rates are uniform, said selector means including means for selectively opening a plurality of said flow paths simultaneously.

15. The device defined in claim 11, further comprising indicator means on said housing for indicating different flow rates at different operative positions of said selector means.

* * * * *

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-	1	("6471675").PN.	USPAT	2003/10/30 13:28
-	1	("5820589").PN.	USPAT	2003/10/30 13:32
-	1	("4838887").PN.	USPAT	2003/10/30 14:15
-	8	("3923060" | "4193397" | "4261356" | "4360019" | "4482346" | "4486190" | "4525165" | "4594058").PN.	USPAT	2003/10/30 13:43
-	35	4838887.URPN.	USPAT	2003/10/30 13:43
-	1	("5281210").PN.	USPAT	2003/10/30 14:09
-	1	("20020087120").PN.	USPAT; US-PGPUB	2003/10/31 10:04
-	127889	duty cycling	USPAT	2003/10/30 14:15
-	6493	(duty cycling) and reservoir and valve	USPAT	2003/10/30 14:16
-	1078	((duty cycling) and reservoir and valve) and accumulator	USPAT	2003/10/30 14:17
-	582	(((duty cycling) and reservoir and valve) and accumulator) and parallel	USPAT	2003/10/30 14:24
-	6	((((duty cycling) and reservoir and valve) and accumulator) and parallel) and implantable and pump	USPAT	2003/10/30 14:50
-	402	(604/151).CCLS.	USPAT	2003/10/30 14:51
-	409674	valve	USPAT	2003/10/30 14:51
-	187	((604/151).CCLS.) and valve	USPAT	2003/10/30 14:51
-	40823	accumulator	USPAT	2003/10/30 14:52
-	5	(((604/151).CCLS.) and valve) and accumulator	USPAT	2003/10/30 14:56
-	59	(604/156).CCLS.	USPAT	2003/10/30 15:10
-	595	(604/246).CCLS.	USPAT	2003/10/30 15:10
-	466	(604/247).CCLS.	USPAT	2003/10/30 15:10
-	254	(604/248).CCLS.	USPAT	2003/10/30 15:10
-	331	(604/249).CCLS.	USPAT	2003/10/30 15:10
-	460	(604/890.1).CCLS.	USPAT	2003/10/31 08:10
-	18814	valve and accumulator	USPAT	2003/10/31 08:22
-	2	((604/890.1).CCLS.) and (valve and accumulator)	USPAT	2003/10/31 08:22
-	317	(604/892.1).CCLS.	USPAT	2003/10/31 08:24
-	2	(valve and accumulator) and ((604/892.1).CCLS.)	USPAT	2003/10/31 08:24
-	334	(604/93.01).CCLS.	USPAT	2003/10/31 08:26
-	2	(valve and accumulator) and ((604/93.01).CCLS.)	USPAT	2003/10/31 08:26
-	497	(604/131).CCLS.	USPAT	2003/10/31 08:28
-	10	(valve and accumulator) and ((604/131).CCLS.)	USPAT	2003/10/31 08:39
-	7	("3840009" | "3923060" | "4013074" | "4056095" | "4077405" | "4137913" | "4146029").PN.	USPAT	2003/10/31 08:36
-	47	4193397.URPN.	USPAT	2003/10/31 08:37

-	2	bolus adj valve	USPAT	2003/10/31 08:41
-	704	bolus and parallel and valve	USPAT	2003/10/31 08:44
-	9275	(bolus or accumulator) and parallel and valve	USPAT	2003/10/31 08:45
-	108	((bolus or accumulator) and parallel and valve) and implantable	USPAT	2003/10/31 08:45
-	1	("5318515").PN.	USPAT; US-PGPUB	2003/10/31 10:08
-	1	("5839467").PN.	USPAT; US-PGPUB	2003/10/31 10:48
-	318	(604/30).CCLS.	USPAT; US-PGPUB	2003/10/31 10:49
-	30	((604/30).CCLS.) and manifold	USPAT	2003/10/31 11:02
-	292	(604/250).CCLS.	USPAT	2003/10/31 11:03
-	70784	"30" and manifold	USPAT	2003/10/31 11:03
-	18	((604/250).CCLS.) and manifold	USPAT	2003/10/31 12:05
-	784	604/31	USPAT	2003/10/31 12:50
-	420	604/32	USPAT	2003/10/31 12:05
-	647	604/34	USPAT	2003/10/31 12:05
-	1366	604/65	USPAT	2003/10/31 12:06
-	715	604/66	USPAT	2003/10/31 12:06
-	1432	604/67	USPAT	2003/10/31 12:06
-	218	(604/31).CCLS.	USPAT	2003/10/31 12:07
-	118	(604/32).CCLS.	USPAT	2003/10/31 12:06
-	149	(604/34).CCLS.	USPAT	2003/10/31 12:06
-	432	(604/65).CCLS.	USPAT	2003/10/31 12:06
-	194	(604/66).CCLS.	USPAT	2003/10/31 12:06
-	485	(604/67).CCLS.	USPAT	2003/10/31 12:07
-	86271	manifold	USPAT	2003/10/31 12:07
-	14	manifold and ((604/34).CCLS.)	USPAT	2003/10/31 12:07
-	7	manifold and ((604/66).CCLS.)	USPAT	2003/10/31 12:07
-	22	manifold and ((604/67).CCLS.)	USPAT	2003/10/31 12:07
-	15	manifold and ((604/31).CCLS.)	USPAT	2003/10/31 12:07
-	5	manifold and ((604/32).CCLS.)	USPAT	2003/10/31 12:09
-	29	manifold and ((604/65).CCLS.)	USPAT	2003/10/31 12:11